RVD2008-31

Re-evaluation Decision

Propylene Glycol

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Overview

Re-evaluation Decision

After a re-evaluation of propylene glycol, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of the product containing propylene glycol for sale and use in Canada.

An evaluation of available scientific information found that the product containing propylene glycol does not present unacceptable risks to human health or the environment when used according to label directions.

The regulatory approach for the re-evaluation of propylene glycol was first presented in Proposed Re-evaluation Decision PRVD2008-17, *Propylene Glycol,* a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of propylene glycol as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-17.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program,* presents the details of the re evaluation activities and program structure.

Propylene glycol, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Re-registration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision for the use of propylene glycol in Canada. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated propylene glycol and published its conclusions in a 2006 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-17, *Propylene Glycol.*

What Is Propylene Glycol?

Propylene glycol is a hard surface sanitizer used to control germs on household surfaces. Homeowners can apply propylene glycol by spraying the ready-to-use solution at the target area and then wiping the sprayed area.

Health Considerations

Can Approved Uses of Propylene Glycol Affect Human Health?

Propylene glycol is unlikely to affect your health when used according to the revised label directions.

People could be exposed to propylene glycol by applying it on surfaces or if they are in contact with treated surfaces. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that propylene glycol was unlikely to affect human health. These conclusions apply to Canada.

Environmental Considerations

What Happens When Propylene Glycol Is Introduced Into the Environment?

Propylene glycol is unlikely to affect non-target organisms when used according to the label directions.

The USEPA concluded that the re-registration of propylene glycol was acceptable. These conclusions also apply to Canada.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of propylene glycol, the PMRA is not requiring further risk-reduction measures for product labels.

Other Information

Any person may file a notice of objection regarding this decision[3] on propylene glycol within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.